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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,747

01/10/2005

Masahiko Koike

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,747	Applicant(s) KOIKE ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10 Jan. 2005, 8 Apr. 2005 and 23 May 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

Applicant's election without traverse of Group I, claims 1, and 3-10, in the reply filed on 7 January 2008 is acknowledged.

It is further acknowledged Applicants' assertion that the Examiner made an election of species requirement, requiring Applicant to select a particular species (page 1, Response). While no such election requirement was made, the Examiner recognizes Applicants' specification of metformin hydrochloride as the active ingredient, ethanol as the alcohol organic solvent, and polyvinylpyrrolidone (PVP) as the coating base.

Claims 2, 11 and 12 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7 January 2008.

The remaining claims 1 and 3-10 are presented and represent all claims under consideration.

Priority

This application is the National Stage filing of International Patent Application No. PCT/JP03/08790, filed 10 July 2003, and Japanese Foreign Application 2002-203119, filed 11 July 2002. Examiner finds that Applicant's filing does not meet the priority requirements for the International Application as well as the Foreign Application.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 11 July 2002. It is noted, however, that applicant has not filed a certified copy of the 2002-203119 application as required by 35 U.S.C. 119(b).

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

As such it is determined that the earliest effective U.S. filing date to be 10 January 2005.

Information Disclosure Statement

Three Information Disclosure Statements filed 10 January 2005, 8 April 2005, and 23 May 2005 are acknowledged and have been reviewed.

Specification

The abstract of the disclosure is objected to because it employs the phrase "and the like". Correction is required. See MPEP § 608.01(b).

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. **The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.**

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "A production method of a coated preparation" is unclear because it is not immediately discernible whether the claim is drawn to a production method that *uses* a coated preparation or *manufactures* it.

The recitation "coating with a dispersion of..." is vague and indefinite because it is not clear exactly what part of the preparation is being coated (i.e. individual particles or a tablet coating).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cutie et al. (WO 91/82875).

The instant claims are drawn to a method of producing a coated preparation that comprises a coating dispersed with pioglitazone hydrochloride in an organic solvent as well as a coating base which is soluble in said organic solvent (claims 1 and 10). Dependent claim 3 further limits the coated preparation to one that has a core containing an active agent (e.g. in addition to the active agent present in the coating). Dependent claims 4, 5 and 6, further limit the active ingredient to a therapeutic agent for diabetes, a biguanide and metformin hydrochloride, respectively. Dependent claim 7 further limits the organic solvent of claim 1 to an alcohol.

Cutie et al. teaches in claim 8, a method for producing a combined formulation of pioglitazone and metformin comprising a) forming a core of the metformin and b) depositing a layer of pioglitazone hydrochloride on at least a portion of the surface of said core. The independent claims 1 and 10 of the instant application recite "coating with a dispersion of pioglitazone hydrochloride". The broadest reasonable interpretation of this recitation is that the pioglitazone hydrochloride, by virtue of being "dispersed" throughout the coating, covers "at least a portion of the surface of the core". Cutie et al. defines "metformin" to mean the base compound as well as its pharmaceutically acceptable salts, including metformin hydrochloride (pg. 1, lines 27-29). Polyvinyl alcohol is taught as a biodegradable material further included in the coating of the dosage form (pg. 7, lines 21-27).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. (U.S. Patent 6,031,004) in view of Cutie et al. (WO 91/82875).

The instant claims are drawn to a method of producing a coated preparation that comprises a coating dispersed with pioglitazone hydrochloride in an organic solvent as well as a coating base which is soluble in said organic solvent, as described above. Dependent claim 8 further defines the organic solvent of claim 1 as ethanol and claim 9 further limits the “coating base soluble in organic solvents” to polyvinylpyrrolidone (PVP).

Timmins et al. teaches the preparation of coated formulations of metformin salts (Examples –10, col. 2, lines 26-33), where the tablet cores also include a coating layer which further one or more film-formers or binders (col. 5, lines 38-43). Binders taught include polyvinylpyrrolidone (col. 5, lines 15-17). The film formers of the coating are taught to be

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applied from a solvent system containing one or more solvent such as ethyl alcohol (col. 5, lines 53-55). Timmins also teaches that the thiazolidinedione oral anti-diabetic agent pioglitazone is employed in combination with the metformin salt (col. 3, lines 59-64). However, pioglitazone is not expressly taught as a coating or as being dispersed within the coating of the dosage.

Cutie et al. teaches a method for producing a combined formulation of pioglitazone and metformin, as described above, wherein pioglitazone is taught to be deposited on at least a portion of a surface of the core.

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to shift the position of the pioglitazone hydrochloride within the composition from being generally combined with metformin salts, as practiced by Timmins et al., to being dispersed within the coating that surrounds the metformin salt core, as practiced by Cutie et al. with a reasonable expectation of manufacturing a coated dosage form capable of delivering dual anti-diabetic active ingredients to diabetes patients. Such would have been obvious in the absence of evidence to the contrary because Cutie et al. teach that the creation of a formulation where both medicaments create a synergistic effect with one another to manage diabetes (pg. 1, lines 16-19). It is also taught that variation in the resulting coated core formulation may serve to alter the release profile of the dosage, thus extending the time period of a patient's single dosage treatment.

No claims allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey T. Palenik
Patent Examiner

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615